

Serial No. 09/777,091

PATENT

- 1        55. (Amended) An implantable valve for a bodily passage of tubular
- 2        shape, comprising:
  - 3              a support frame configured for expansion to conform to a wall of the
  - 4              bodily passage, said support frame when expanded providing a plurality
  - 5              of side elements each defining a path extending at least partially
  - 6              longitudinally along the wall and at least partially circumferentially around
  - 7              the wall,
  - 8              a plurality of leaflets comprising an extracellular collagen matrix
  - 9              material, each leaflet thereof having a body extending from a wall-
  - 10             engaging outer edge to an inner edge proximate a corresponding inner
  - 11             edge of at least one other leaflet of the plurality of leaflets,
  - 12             the inner edges of said plurality of leaflets cooperable to define an
  - 13             opening therebetween to permit fluid flow in a first direction along the
  - 14             bodily passage, and further cooperable to engage each other sufficiently to
  - 15             restrict fluid flow in a second direction opposing the first direction,
  - 16             the outer edge of each one of the plurality of leaflets attached along
  - 17             one side element of said plurality of side elements and thereby adapted to
  - 18             directly engage the wall of the bodily passage therearound and provide
  - 19             ingrowth of adjacent native tissue into the extracellular collagen matrix
  - 20             material.

Please add the following claims:

- 1        56. (New) The implantable valve of claim 55 wherein the collagen matrix
- 2        material comprises submucosal tissue.
- 1        57. (New) The implantable valve of claim 55 wherein the collagen matrix
- 2        material comprises small intestinal submucosa.

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1       58. (New) An implantable valve for a bodily passage of tubular shape,  
2       comprising:

3              a frame that includes a plurality of legs, each of the legs originating  
4       from a pair of bends located about a first end of the implantable valve, and  
5       extending in an opposite direction therefrom, each of the plurality of legs  
6       terminating at a second end of the implantable valve opposite the first end  
7       such that the plurality of legs generally assume a serpentine configuration  
8       along the circumference of a bodily passage when situated therein,

9              a plurality of leaflets, each leaflet comprising a covering that includes  
10       one or more flexible materials, the leaflet including a body that comprises  
11       a wall-engaging outer edge and an inner edge, the outer edge at least  
12       partially attached to, and reinforced by one of the plurality of legs, the outer  
13       edge and the associated leg adapted to sealingly engage the inner wall of  
14       the bodily passage,

15              wherein the body of the leaflet extends inward from the wall of the  
16       bodily passage and extending toward the first end of the implantable valve  
17       where it terminates at the inner edge, the body and inner edge traversing  
18       the lumen of the bodily passage when situated therein and being  
19       configured such that the leaflet is cooperable with at least one other leaflet  
20       to define an opening that permits positive flow of fluid therethrough in a  
21       first direction, while the plurality of leaflets are further adapted to trap  
22       between the leaflets and the inner wall of the bodily passage fluid flowing  
23       in a second direction opposite the first direction and seal against one  
24       another to restrict fluid flow in said second direction; and

25              wherein the frame is adapted to assume a plurality of configurations,  
26       a first configuration of the plurality of configurations being a generally flat  
27       plane.

1       59. (New) An implantable valve for a bodily passage of tubular shape,  
2       comprising:

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3           a frame that includes a plurality of legs, each of the legs originating  
4         from a pair of bends located about a first end of the implantable valve, and  
5         extending in an opposite direction therefrom, each of the plurality of legs  
6         terminating at a second end of the implantable valve opposite the first end  
7         such that the plurality of legs generally assume a serpentine configuration  
8         along the circumference of a bodily passage when situated therein,

9           a plurality of leaflets, each leaflet comprising a covering that includes  
10        one or more flexible materials, the leaflet including a body that comprises  
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13        edge and the associated leg adapted to sealingly engage the inner wall of  
14        the bodily passage,

15        wherein the body of the leaflet extends inward from the wall of the  
16        bodily passage and extending toward the first end of the implantable valve  
17        where it terminates at the inner edge, the body and inner edge traversing  
18        the lumen of the bodily passage when situated therein and being  
19        configured such that the leaflet is cooperable with at least one other leaflet  
20        to define an opening that permits positive flow of fluid therethrough in a  
21        first direction, while the plurality of leaflets are further adapted to trap  
22        between the leaflets and the inner wall of the bodily passage fluid flowing  
23        in a second direction opposite the first direction and seal against one  
24        another to restrict fluid flow in said second direction; and

25        wherein the frame is adapted to assume a plurality of configurations,  
26        a first configuration of the plurality of configurations being a generally flat  
27        plane; and

28        wherein the covering includes two leaflets such that when the frame  
29        in the generally flat configuration generally assumes a diamond shape with  
30        the inner edges of the two leaflets defining a slit therebetween.

Remarks